



LAWRENCE  
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## Document Review

Quality Implementing Procedure ID:  
OSTI-LLNL-QIP-6.1, Rev.0, Mod.0

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# DOCUMENT REVIEW

*Quality Implementing Procedure ID: OSTI-LLNL-QIP-6.1, Rev. 0, Mod. 0*

*Effective: 2/25/05*

## 1. PURPOSE

This Quality Implementing Procedure (QIP) describes the requirements for conducting and documenting reviews of Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) documents. This process is intended to produce technically sound documents that will meet the technical and administrative requirements of the OSTI-LLNL Project.

This procedure describes review requirements by LLNL that are in conjunction with reviews required in applicable governing OSTI-LLNL-QIPs. Any additional required reviews by external organizations (e.g., other OSTI participants, the U.S. Department of Energy [DOE], the Office of Quality Assurance [OQA]) shall be conducted as directed by the governing procedure or as directed by instructions accompanying the document.

## 2. SCOPE

This QIP has been prepared in accordance with OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*, and applies to all OSTI-LLNL scientific documents subject to the DOE Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description (QARD)*, DOE/RW-0333P including:

- Technical Reports
- Model Reports
- Scientific/engineering journal articles
- LLNL reports
- Scientific notebooks
- Data
- Software qualification documentation
- Technical Work Plans (TWP)
- QA Plan
- QIPs
- Technical Implementing Procedures (TIP)

- Other OSTI-LLNL documents not listed here if reviews are determined to be necessary by the OSTI-LLNL Project Manager (PM).

This QIP applies to the activities of the Originator (or first or lead author of a document), independent Technical Reviewer, QA Reviewer, Principal Investigator (PI), Deputy PM (DPM), and the PM during the review process.

Reviews performed according to this procedure are in addition to any reviews required by other governing procedures identified in Section 3.1.1 (e.g., Checker). The Checker Review may be referenced, but is not specifically described in this procedure.

### 3. PROCEDURE

#### 3.1 Kinds of Reviews Required for Various Technical Documents:

Alpha revision designators (e.g., Draft A, Draft B, etc.) shall be used to denote each draft of a document, from the development of the initial issue up to approval of the document. The following technical and QA review requirements are in effect for OSTI-LLNL scientific documents:

**3.1.1 Technical Reports, Model Reports:** Technical and Model Reports are checked and reviewed in accordance with OSTI-LLNL-QIP-SIII.1, *Technical Reports*, and OSTI-LLNL-QIP-SIII.2, *Model Reports*, respectively. Additionally, a minimum of one OSTI-LLNL Technical Reviewer and one QA Reviewer shall be assigned to review all OSTI-LLNL Technical and Model Reports in accordance with this procedure.

Proper revision control shall be maintained on all drafts of the document as they move through technical review, QA review and all other required reviews (e.g., the Checker) as described in Section 3.2.6. The Review Record (Attachment 2) and Comment Sheet (Attachment 4) shall be used to document the OSTI-LLNL technical and QA reviews. The final review concurrence shall be documented on the Review Record (Attachment 2).

This procedure provides for an evaluation process for Technical and Model Reports identified as a DOE deliverable to assure the technical adequacy of the document, and the traceability and accuracy of source information as follows:

- A. **Technical Review:** A technical content review shall be conducted by an independent Technical Reviewer from the same technical functional area as the Originator. The Technical Reviewer is assigned by the PM/DPM (or designee) who may direct that the Technical Review be completed before Checking, or that they be performed concurrently. The Technical Reviewer shall conduct an overall assessment of the technical quality of the document, including the document's technical adequacy, correctness, completeness, accuracy, applicability to the issues being addressed, and compliance with requirements provided in the governing procedure. The governing procedure and Technical Review Criteria provided within (e.g., OSTI-

LLNL-QIP-SIII.1, OSTI-LLNL-QIP-SIII.2) shall be used in the conduct of the review. Additional technical review criteria may be identified on the Review Record, as deemed appropriate by the PM/DPM (or designee).

- B. QA Review: Prior to finalizing a Technical or Model Report, a QA review shall be conducted by an independent QA Reviewer who is knowledgeable of the overall procedural requirements. The QA Reviewer is assigned by the PM/DPM or designee to ensure that quality requirements (e.g., compliance with governing procedural requirements, management directives, associated errata, condition reports, etc.) are adhered to. Additional QA review criteria may be identified on the Review Record, as deemed appropriate by the PM/DPM (or designee).

**3.1.2 Scientific Notebooks:** Pertinent sections of scientific notebooks that support a Technical and Model Report, or data submittal shall be technically reviewed by a Technical Reviewer. In addition, as a minimum, annually or at notebook closeout, a Technical Review of scientific notebooks shall be performed for pertinent sections that have not been previously reviewed. The reviewer shall be independent of the work produced and be qualified to retrace the described work to confirm the results or repeat the work and achieve comparable results without recourse to the original investigator. The Technical Reviewer shall review the scientific notebook for technical adequacy, correctness, completeness, accuracy, applicability to the issues being addressed, and compliance with OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*, and Scientific Notebook Review Criteria identified within. The Review Record, Applicable Reference Information, and Comment Sheet (Attachments 2, 3, and 4, respectively of this procedure) shall be used to document the review of notebooks.

Compliance Reviews of scientific notebook shall be performed by a QA Reviewer annually, and at notebook closeout in accordance with OSTI-LLNL-QIP-SIII.0. The Compliance Review Worksheet provides criteria that shall be used to document the review per OSTI-LLNL-QIP-SIII.0.

**3.1.3 Data submitted to the Technical Data Management System:** Data and pertinent section(s) of identified source documents (e.g., scientific notebook pages) shall be reviewed by a Technical Reviewer prior to submittal to the Technical Data Management System (TDMS). The data reviewer shall be technically competent and independent of the data originator. Data reviewers shall use the Data Review Criteria identified in OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*; reviews of associated notebook pages shall use the Scientific Notebook Review Criteria identified in OSTI-LLNL-QIP-SIII.0. The reviews shall be documented on the Review Record (Attachment 2) and Comment Sheet (Attachment 4). Associated software used for the data analysis shall be documented in accordance with OSTI-LLNL-QIP-SI.0, *Software Management*. The Key Technical Data Traceability (KTDT) form in OSTI-LLNL-QIP-SIII.3 shall be used to identify the documentation supporting the data (e.g., applicable

scientific notebook pages, computer codes, etc.). The review documentation of data and associated source documents shall be transmitted to the Technical Data Coordinator. The final technical data shall be submitted to the TDMS in accordance with the OSTI-LLNL-QIP-SIII.3. All related records shall be forwarded to the Records Coordinator for submittal to the Records Center (RC). Documentation of transmittal of data to the TDMS, or the documentation accession number, shall be included in the corresponding scientific notebook.

**3.1.4 Data Qualification Reports:** Data qualification may be documented in a Data Qualification Report prepared in accordance with OSTI-LLNL-QIP-SIII.4, *Qualification of Unqualified Data*, or as part of a Technical or Model Report prepared in accordance with OSTI-LLNL-QIP-SIII.1 or OSTI-LLNL-QIP-SIII.2. The Data Qualification Report shall be reviewed by a Checker using methodology described in the governing procedures identified above. In addition, an independent Technical and QA Reviewer shall review the data qualification documentation in accordance with this procedure. The Technical Reviewer shall be technically competent and independent of the data originator, and review the Data Qualification Report for technical adequacy, correctness, completeness, accuracy, applicability to the issues being addressed, and consistency with the applicable planning document (i.e., Technical Work Plan (TWP) or Data Qualification Plan generated for the data qualification). The QA Reviewer shall review for compliance with the governing procedure and the planning document. The Review Record (Attachment 2) and Comment Sheet (Attachment 4) shall be used to document the review.

**3.1.5 Software Qualification Documentation:** Each element or life cycle phase of qualification documentation (e.g., Level A Requirements Document [RD], Design Document [DD], Validation Test Plan [VTP], Installation Test Plan [ITP], Users Manual [UM], and Validation Test Report [VTR]); and Level B: Software Management Report [SMR]) shall be reviewed by an independent Technical Reviewer and the Software Coordinator (or designee).

The Technical Reviewer is assigned by the PM/DPM (or designee) to provide an overall assessment of the technical quality of the document, including the document's technical adequacy, correctness, completeness, accuracy, applicability to the issues being addressed, and compliance with technical review criteria identified in OSTI-LLNL-QIP-SI.0, *Software Management*. The Technical Reviewer shall be independent of all prior development and testing activities for the software. Review assignment and criteria shall be documented on a Review Record (Attachment 2). Comments shall be documented on Comment Sheet(s) (Attachment 4), a Review Copy Mark-up, or electronically. The purpose of the reviews will be to verify that the products of, and/or results generated by a given phase of the software development cycle fulfills the requirements imposed by the previous phase (e.g., comparison of the proposed design against the document requirements to ensure that all requirements are addressed in the design).

The Software Coordinator (or designee) shall perform a verification review of all Level A and Level B software documentation to ensure that technical and quality requirements (e.g., compliance with technical and procedural requirements documented in OSTI-LLNL-QIP-SI.0) are adhered to. If the Software Coordinator is associated with the development of the software and will perform the verification review, the Deputy PM shall provide management approval and documented justification thereof. Level A and Level B code reviews shall be documented on a Review Record (Attachment 2) and Comment Sheet (Attachment 4)/electronically/or a review copy.

- 3.1.6 Scientific/Engineering Journals and LLNL Reports:** Submittals to scientific/engineering journals and LLNL reports shall be reviewed by a technically competent, independent Technical Reviewer and a Technical Editor. A QA review is not required. Additional Energy & Environment Directorate review requirements may apply for the LLNL reports and journal articles.

The Review Record (Attachment 2) and Comment Sheet (Attachment 4) or Review Copy mark-up shall be used to document the Technical Review. Technical Reviewer shall consider, at a minimum, whether the document is correct, technically adequate, complete, and accurate.

**3.1.7 Technical Work Plans, the QA Plan, Quality Implementing Procedures, Technical Implementing Procedures**

- A. OSTI-LLNL TWP's shall be developed, reviewed and approved in accordance with OSTI-LLNL-QIP-2.2, *Planning for Science Activities*. A Technical and QA Review shall be performed prior to final approval. The Review Record and Comment Sheet (Attachments 2 and 4, respectively) of this procedure shall be used to document these reviews. Technical Reviewers shall consider, at a minimum, whether the document is correct, technically adequate, complete, accurate, and in compliance with criteria identified in OSTI-LLNL-QIP-2.2 and consistent with the DOE Guidance and Funding Memorandum authorizing OSTI-LLNL work. Compliance with QA requirements described in OSTI-LLNL-QIP-2.2 and the Guidance and Funding Memorandum shall be used as a basis for the QA review.
- B. The OSTI-LLNL QA Plan shall be reviewed by one Technical Reviewer (the Deputy PM [or designee]), a QA Reviewer, and be finally approved by the PM in accordance with OSTI-LLNL-QIP-5.0. The Technical and QA Reviewer shall use the Review Record and Comment Sheet (Attachments 2 and 4, respectively) to document these reviews, and use the QA Plan Criteria, current OSTI-LLNL-QIPs, and compliance with OSTI-LLNL-QIP-5.0 as a basis for the reviews. The QA Reviewer also reviews the plan for compliance with QAP requirements.
- C. QIPs shall be reviewed by one Technical Reviewer, a QA Reviewer, and be finally approved by the PM (or designee) in accordance with OSTI-LLNL-QIP-5.0. The QA Reviewer shall ensure that overall OSTI-LLNL QA program requirements are adhered to. The Technical and QA Reviewer shall

use the Procedure Review Criteria and QA Review Criteria, respectively, and compliance with requirements described in the applicable governing procedures. The QA Reviewer also reviews the procedure for compliance with QAP requirements.

- D. TIPS shall be reviewed by two Technical Reviewers (one of whom is the Principal Investigator [PI] if the PI is not the originator), a QA Reviewer, and be finally approved by the PM (or designee) in accordance with OSTI-LLNL-QIP-5.0. The Technical and QA Reviewer shall use the criteria identified for QIPs above, as appropriate.

The same review requirements shall be in effect for any revisions as required by the applicable governing procedures. Revisions and modifications to the requirements of OSTI-LLNL-QIPs and TIPS shall follow the requirements of OSTI-LLNL-QIP-5.0.

### 3.2 Initiation of the Review Process

Required OSTI-LLNL reviews as described in Section 3.1 shall be performed as described below. The Deputy PM may direct that the Technical Review be completed before Checking, or that they be performed concurrently.

The following requirement steps apply to all technical and QA reviews. As such, Technical Reviewer, QA Reviewer may be substituted where Reviewer is identified below, as appropriate.

- 3.2.1** The document/data **Originator** (i.e., first or lead author, referred to as Originator throughout this QIP) shall have overall responsibility for the content of the document and shall notify the Deputy PM when a document is complete and ready for review.
- 3.2.2** The **Originator** shall schedule the review giving enough lead-time to allow adequate review and documentation of the process. The Originator shall be the Review Coordinator unless designated otherwise by the Deputy PM. The Originator of a document begins the review process by requesting the Deputy PM (or designee) to appoint the Reviewer(s). The Originator may recommend a potential reviewer(s) to the Deputy PM (or designee).
- 3.2.3** The **PM/DPM** (or designee) shall appoint a Technical Reviewer(s) who is technically competent in the subject area being reviewed and who did not directly participate in the authorship of the document or portion of the document (e.g., chapter) under review. To be qualified as an independent Technical Reviewer, an individual shall be technically qualified (i.e., a peer of the Originator) in the scientific document subject area(s), or be similarly qualified in a user research subject area. The **PM/DPM** (or designee) shall select a sufficient number of Technical Reviewers to ensure that all areas of expertise addressed in the document are adequately reviewed. The selection of the Technical Reviewer(s) responsible for reviewing the document shall be documented on the Review Record, as described in Attachment 2.

- 3.2.4** Prior to performance of a review, the **Originator** (or designated Review Coordinator) shall ensure that the Technical Reviewer, and QA Reviewer qualifications are documented and approved/dated by the PM/DPM on the Reviewer Qualification Verification Statement (RQVS) or equivalent (Attachment 1). This need only be done once for each Technical or QA Reviewer, not for each review, as long as qualifications are relevant for the assigned documents. The OSTI-LLNL Training Coordinator shall maintain the RQVS. All reviewers shall follow the latest revision of this procedure, and the latest revision of the applicable governing procedure, to perform the review.
- 3.2.5** Each designated Technical Reviewer from applicable areas of expertise as identified by the PM/DPM (Section 3.2.3) shall review the document according to the established review criteria. Revisions to a document shall also be reviewed by the same technical disciplines.
- 3.2.6** The document/data **Originator** (or designated Review Coordinator) shall initiate the Review Record by following the instructions given for Attachment 2. Alpha revision designators shall be used to denote each draft reviewed from the initial issue up to approval of the document by the required internal and external reviewers.

The Originator shall provide the reviewer with:

- a copy of the document to be reviewed (hereafter referred to as the Review Copy)
- the Review Record (Attachment 2)
- associated review criteria

Criteria shall be established and recorded on the Review Record in accordance with the governing procedure and Section 3.1 of this procedure. As a minimum, technical reviews shall include consideration of the applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements of the document under review. The technical or QA review criteria may be supplemented as deemed appropriate by the PM/DPM.

- Comment Sheet (Attachment 4) and any additional pertinent background information (e.g., TWP) if information is not readily available to the reviewer.
- Applicable Reference Information (Attachment 3) listing the associated scientific notebooks and other source documents, if applicable; or the KTDT form from OSTI-LLNL-QIP-SIII.3 for data reviews. The scientific notebook pages identified on these forms shall be included as a part of the review.

### 3.3 Performance of Review

**3.3.1** The **Reviewer(s)** shall consider all aspects of the document/data under review and evaluate the document(s) according to the review criteria identified on the Review Record (Attachment 2).

- A. The **Reviewer** shall clearly and legibly write all comments and any suggested resolution, if applicable, on the Comment Sheet (Attachment 4), on the Review Copy, or by an electronic method. If a mark-up copy is used, print name and date on the title page, and identify it as a "Review Copy". If comments are provided electronically, each comment shall be numbered and reference the applicable section/paragraph. All technical comments shall be considered mandatory. Editorial comments that do not affect the content of the report, such as spelling, grammar, or syntax, are considered non-mandatory, and may be documented on the Review Copy itself.
- B. If there are no comments, the **Reviewer** shall mark the Comment Sheet (Attachment 4) as such or document this on the Review Copy or electronically.
- C. When the review is complete, the **Reviewer** shall sign and date the Review Record (Attachment 2) and return it along with attached Comment Sheet(s) (Attachment 4), Review Copy mark-up, or electronic method and any supplementary background documents to the Originator.

During resolution of comments and development of the Concurrence Draft, close communication between the Originator and the Reviewer(s) is encouraged. It may also be advisable for the Reviewers to communicate among themselves if more than one Reviewer is assigned to a document, particularly if conflicting comments have developed.

### 3.4 Response to Reviewer Comments

**3.4.1** The document **Originator** (or designee) shall consider and respond to all technical comments. If the Comment Sheet is used, Originator responses shall be documented in the "Response" column of the Comment Sheet (Attachment 4). If a Review Copy markup is used, responses shall be noted on the Review Copy next to each comment. If an electronic method is used, comment resolution shall be identified electronically with sequential numbers for each comment. Additional notes may be submitted if needed and should be referenced on the review documentation.

The originator need not accept each comment, but the rejection of specific comments and the reasons for rejection shall be recorded on the Comment Sheet, Review Copy mark-up, or electronically. Editorial comments need no response. The Originator shall revise the draft document as discussed in the response and sign the Review Record. The resulting Concurrence Draft of the

document, Review Record, and attached Comment Sheet(s), Review Copy mark-up, or electronic copy shall be returned to the reviewer(s) for technical comment resolution and concurrence.

**3.4.2** The **Reviewer(s)** shall:

- A. Review the responses on the Comment Sheet, Review Copy mark-up, or electronic copy and compare the response to the Concurrence Draft and any associated documentation; evaluate the responses to technical comments for acceptability and review the revised document/data set to ensure that the Concurrence Draft meets the review criteria, including any new criteria or review instructions that may have resulted from the initial review.
- B. Indicate acceptance of the Originator's response by initialing and dating the "Accept" column of the Comment Sheet, or reject by leaving the "Accept" column blank. If responses are provided on a Review Copy Markup, initial and date near the response if acceptable, otherwise indicate "reject." If responses are provided electronically indicate acceptance or rejection electronically. If all technical comments are accepted, the Reviewer shall ensure that there is a record of response and resolution of all technical comments, and indicate this by signing the "Concurrence" section of the Review Record (Attachment 2).

**3.4.3** Direct interaction between the **Originator** and **Reviewer(s)** is encouraged to resolve outstanding issues. If the reviews are performed concurrently and conflicting comments are generated, it is the responsibility of the Originator (or designated Review Coordinator to assure the comments are resolved satisfactorily with the reviewers. When such issues cannot be resolved, they shall be referred to successively higher levels of management and ultimately to the PM (or designee) for resolution.

**3.4.4** The **Originator** and **Reviewer(s)** shall resolve unacceptable responses and document the resolution thereof on additional Comment Sheets (if needed) or memorandum to be included in the review package, or elevate disputed issues to appropriate management, if necessary.

**3.4.5** The **Resolving Manager** shall discuss each unresolved technical comment with the parties involved and make the determination of their resolution. The resolution shall be documented on the Comment Sheet, Review Copy mark-up, or electronically. Once all issues are resolved, the Resolving Manager shall indicate the satisfactory final resolution of all items by signing and dating the "Accept" column of the Comment Sheet and the "Dispute Resolution" section of the Review Record.

### **3.5 Approvals**

Upon comment resolution, the **Originator** shall:

**3.5.1** Produce the final document by changing the alphanumeric designator to a numeric designator (the initial designator is 00 and subsequent revisions are 01, 02, etc.).

**3.5.2** Obtain approval signatures as follows:

- TWPs, Technical and Model Reports - in accordance with requirements of the governing procedure
- QA Plan – QA Manager, the Deputy PM and PM
- QIPs and TIPs – Originator, Technical Reviewers, QA Reviewer, and PM on the procedure approval sheet

### **3.6 Data and Records Submittal**

The **Originator** shall transfer reviewed data to the Technical Data Coordinator for submittal to the TDMS in accordance with the OSTI-LLNL-QIP SIII.3Q. A KTDT form which identifies the data supporting documentation, and the review forms shall accompany the data submittal. The **Technical Data Coordinator** shall ensure that all the applicable records identified in Section 4.1 below and in the applicable governing procedure, are submitted to the OSTI-LLNL Records Coordinator for maintenance.

Approved OSTI-LLNL controlled documents (i.e., TWPs, QIPs, TIPs, Technical Reports, Model Reports) shall be submitted to the Records Coordinator for distribution according to OSTI-LLNL-QIP-6.0, *Document Control*. Completed documents and associated reviews shall be transmitted to the Records Coordinator for maintenance in accordance with OSTI-LLNL-QIP-17.0, *Records Management*.

## **4. RECORDS**

The records listed in Sections 4.1 and 4.2 shall be collected and submitted to the RC in accordance with OSTI-LLNL-QIP-17.0, as individual records or included in a records package, as specified.

### **4.1 QA Records**

#### Records Package

- Final reviewed documents/data
- Review Record and Comment Sheet(s)/Review Copy Mark-up (if Comment Sheet not used)/electronically documented comments
- Applicable Reference Information, if scientific notebooks reviewed; or KTDT form if data reviewed

#### Individual

- Reviewer Qualification Verification Statement

## 4.2 Non-QA Long-Term Records

Review Drafts.

## 4.3 Non-QA Short Term Records (three years or less<sup>1</sup> retention)

None.

## 5. RESPONSIBILITIES

- 5.1 The **Project Manager (PM)** (or designee) is responsible for the approval of the QA Plan, QIPs and TIPs, TWPs, Technical/Model Reports, and the final disposition of disputed comments.
- 5.2 The PM/DPM (or designee) is responsible for appointing Checkers/Technical/QA Reviewers for OSTI-LLNL documents on the basis of education, training and experience. The PM/DPM (or designee) is also responsible for performing the technical review of the QA Plan, and assigning specific review criteria as deemed appropriate.
- 5.3 The **Quality Assurance (QA) Manager** (or designee) is responsible for providing assistance/guidance to staff members in the review process.
- 5.4 The document **Originator** (first or lead author, referred to as Originator throughout this QIP) or **Review Coordinator** (if designated by the Deputy PM to be someone other than the Originator) is responsible for scheduling and coordinating the review process. The Originator/Review Coordinator, together with the Training Coordinator, are responsible for ensuring that all Technical and QA Reviewers, who do not have previously documented qualifications on file, fill out the RQVS form prior to performing the review. The Originator/Review Coordinator shall complete the Review Record, distribute copies of the review forms and the document being reviewed to the designated Technical and QA Reviewers along with applicable pages of scientific notebooks, background information, and data to be reviewed. Upon return of reviews, the Originator shall respond to all technical comments made by the reviewers.
- 5.6 The **Training Coordinator** is responsible for maintenance of the RQSV forms.
- 5.7 **Technical Reviewer(s)** is responsible for reviewing the document, providing written comments on the Comment Sheet or draft documentation, and evaluating/accepting Originator responses. Comments shall be returned to the Originator in a timely manner.
- 5.8 The **QA Reviewer** is responsible for reviewing the QA Plan, QIPs, TIPs, planning documents, Technical/Model Reports, and Data Qualification Reports for compliance with applicable OSTI-LLNL QA Program requirements.

## 6. ACRONYMS AND DEFINITIONS

### 6.1 Acronyms

|       |  |
|-------|--|
| DD    | Design Document                                  |
| DOE   | U.S. Department of Energy                        |
| DPM   | Deputy Project Manager                           |
| ITP   | Installation Test Plan                           |
| KTDT  | Key Technical Data Traceability                  |
| LLNL  | Lawrence Livermore National Laboratory           |
| OCRWM | Office of Civilian Radioactive Waste Management  |
| OQA   | Office of Quality Assurance                      |
| OSTI  | Office of Science & Technology and International |
| PI    | Principal Investigator                           |
| PM    | Project Manager                                  |
| QA    | Quality Assurance                                |
| QAP   | Quality Assurance Plan                           |
| QARD  | Quality Assurance Requirements and Description   |
| QIP   | Quality Implementing Procedure                   |
| RC    | Records Center                                   |
| RD    | Requirements Document                            |
| RQVS  | Reviewer Qualification Verification Statement    |
| SMR   | Software Management Report                       |
| TDMS  | Technical Data Management System                 |
| TIP   | Technical Implementing Procedure                 |
| TWP   | Technical Work Plan                              |
| UM    | Users Manual                                     |
| VTP   | Validation Test Plan                             |
| VTR   | Validation Test Report                           |

### 6.2 Definitions

**Concurrence Draft:** A draft of a scientific document or data set that has been revised to incorporate comments generated by Reviewer(s), and that is considered by the document/data Originator to be ready for concurrence and approval.

**Data Originator:** Individual responsible for collecting, developing, and assembling scientific data.

**Editorial Comments:** Comments made to a document such as correcting grammar, spelling, or obvious typographical errors; renumbering sections or attachments (as long as the renumbering does not affect the chronological sequence of work); modifying the title or number of the document (as long as the fundamental process is not changed); updating organizational titles (as long as responsibilities are not changed); or making other corrections or clarifications of intent that do not alter the results or the way a document is used.

**Governing Procedure:** The procedure that defines the requirements for the development of a document or data set. The governing procedure typically invokes

other procedures that define the requirements for certain steps, such as document review.

**Model:** A model representation of a system, process, or phenomenon, along with any hypotheses required to describe the process or system or explain the phenomenon, often mathematically.

**Originator:** The first or lead author who has overall responsibility for preparing a scientific document and overseeing persons who have made material contributions to the work and composition, and who accepts professional responsibility for its contents.

**Review Draft:** A draft (e.g., Technical Review draft) of a scientific document or data set including text, figures, tables and any supporting appendices, that is considered by the document/data Originator to be ready for review.

**Technical Report:** As it pertains to scientific investigation, a document that presents scientific information such as data, analysis, interpretations, or conclusions.

**Technical Reviewer:** A technically competent individual, other than the Originator, from the same technical area as the Originator, assigned by the Deputy PM, with education, training and experience that allows him/her to understand/evaluate the contents of the document being reviewed. A reviewer shall not have participated in the authorship of the portion of the document (e.g., chapter) under his/her review.

## 7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LLNL-QIP-1.0, *OSTI-LLNL Organization Structure*

OSTI-LLNL-QIP-2.2, *Planning for Science Activities*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP -17.0, *Records Management*

OSTI-LLNL-QIP -SI.0, *Software Management*

OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*

OSTI-LLNL-QIP-SIII.1, *Technical Reports*

OSTI-LLNL-QIP-SIII.2, *Model Reports*

OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*

OSTI-LLNL-QIP-SIII.4, Qualification of Unqualified Data

8. ATTACHMENTS

- Attachment 1 - Reviewer Qualification Verification Statement
- Attachment 2 - Review Record
- Attachment 3 - Applicable Reference Information
- Attachment 4 - Comment Sheet

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0:  
Initial issue.

10. APPROVALS

|  |   |
|--|---|
| <p>Preparer: <u><i>Leigh Gouveia</i></u><br/>         Technical Reviewer: <u><i>QINHONG HU</i></u><br/>         QA Reviewer: <u><i>VICTOR J. BARISH JR</i></u><br/>         Project Manager: <u><i>DAVID B. McCALLEN</i></u></p> | <p>Date: <u><i>2/25/05</i></u><br/>         Date: <u><i>2/25/05</i></u><br/>         Date: <u><i>2/25/05</i></u><br/>         Date: <u><i>2/25/05</i></u></p> |
|--|---|

**OSTI-LLNL\***  
**Reviewer Qualification Verification Statement**  
 (To be signed prior to reviewing)

Technical Reviewer     QA Reviewer

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Organization: \_\_\_\_\_

Technical Expertise: \_\_\_\_\_

Basis of Qualification (Brief Résumé):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

I certify that the above or attached information is correct.

\_\_\_\_\_  
 Technical/QA Reviewer Signature

\_\_\_\_\_  
 Date

The above Technical/QA Reviewer meets the education and experience requirements to perform reviews in the specified area of technical expertise.

\_\_\_\_\_  
 Project or Deputy Project Manager Signature

\_\_\_\_\_  
 Date

\* An equivalent form may be used to document the Reviewer qualifications.

**OSTI-LLNL  
 REVIEW RECORD**

1. QA: \_\_\_\_\_  
 2. Page \_\_\_\_\_ of \_\_\_\_\_

3. Project Manager: \_\_\_\_\_  
 4. Originator/Comment Responder: \_\_\_\_\_

5. Document Title: \_\_\_\_\_

6. Document Identifier: \_\_\_\_\_  
 7. Revision/Mod./Review Draft: \_\_\_\_\_  
 8. Date: \_\_\_\_\_

9. Governing Procedure Number: \_\_\_\_\_  
 10. Governing Procedure Revision/ Mod: \_\_\_\_\_

**REVIEW CRITERIA**

11.  Standard Review Criteria \_\_\_\_\_  
 Specific Review Criteria (QIP, QARD, etc.) \_\_\_\_\_

13. Comment Documentation:  
 Comment Sheets \_\_\_\_\_  
 Review Copy Mark-up \_\_\_\_\_  
 Electronic Method \_\_\_\_\_

Source: \_\_\_\_\_  
 Attached: \_\_\_\_\_  
 Scientific notebook pages associated with technical notebook review (see Attachment 3)\*

| 14. Reviewer | Org./Discipline | Review Criteria | Reviewer | Org./Discipline | Review Criteria |
|--------------|-----------------|-----------------|----------|-----------------|-----------------|
| _____        | _____           | _____           | _____    | _____           | _____           |
| _____        | _____           | _____           | _____    | _____           | _____           |
| _____        | _____           | _____           | _____    | _____           | _____           |

**COMMENTS DUE:**

**REVIEW BY:**

15. Due Date: \_\_\_\_\_  
 17. \_\_\_\_\_  
 Print Name \_\_\_\_\_  
 Signature \_\_\_\_\_  
 Date \_\_\_\_\_

18. \_\_\_\_\_  
 Signature \_\_\_\_\_  
 Date \_\_\_\_\_

16. \_\_\_\_\_  
 Print Name \_\_\_\_\_  
 Signature \_\_\_\_\_  
 Date \_\_\_\_\_

**CONCURRENCE:**

20. Document Concurrence Draft No: \_\_\_\_\_  
 21. Reviewer: \_\_\_\_\_  
 Signature \_\_\_\_\_  
 Date \_\_\_\_\_

DISPUTE RESOLUTION (if applicable):  
 22. Resolving Manager: \_\_\_\_\_  
 Print Name \_\_\_\_\_  
 Signature \_\_\_\_\_  
 Date \_\_\_\_\_

23. Resolving Manager: \_\_\_\_\_  
 Signature \_\_\_\_\_  
 Date \_\_\_\_\_

\*For data reviews include OSTI-LLNL-QIP-SIII.3, Key Technical Data Traceability

## INSTRUCTIONS FOR COMPLETING THE REVIEW RECORD.

### PROJECT MANAGER OR DESIGNEE:

1. Identify the Quality Assurance (QA) designator (for a Q-designated Document/Data, enter "QA"; for a non-QA Document/Data, enter "N/A").
2. Identify the total number of pages for the Review Record (e.g., if 1 page of specific review criteria is included or Attachment 3, Applicable Reference Information, or Key Technical Data Traceability is attached, identify as page 1 of 2).
3. Enter name of the OSTI-LLNL Project Manager.
4. Identify the Document Originator /Comment Responder.
5. Record the title of Document to be reviewed.
6. Record the Document Identifier or number of the Document to be reviewed (e.g., MDL-OSTI-LLNL-000002).
7. Record the proposed revision/modification and draft number, as applicable (e.g., Rev 1 Mod 0, Draft 00A).
8. Record the date the draft Document was generated.
9. Identify the procedure invoking the review. Mark "N/A" if not applicable.
10. Identify the revision/modification, as applicable, of the procedure invoking the review.
11. Identify the standard review criteria that apply, check box and identify the source of the standard review criteria.
12. If specific review criteria apply, mark appropriate box. Identify source where the review criteria can be located (e.g., OSTI-LLNL-QIP-5.0, Rev 0, Mod 0). If specific criteria (other than that identified in source documents ) are attached, mark attached box and include criteria as part of the review record page count. Check box if scientific notebooks are to be reviewed as part of this review (if so, append Attachment 3 and identify notebook ID #/pages to be reviewed). If data are being reviewed append the Key Technical Data Traceability form per OSTI-LLNL-QIP-SIII.3.
13. Check box to identify comment documentation method. Review Copy Mark-up may be used for journal articles. Comment sheets, review copy mark-up or an electronic method may be used for software reviews.
14. Identify the Reviewers, organization/discipline and the standard review criteria (or unique review criteria) assigned to each reviewer. Leave unused lines blank.
15. Assign a due date for the return of the comments.
16. Print name of Originator/Review Coordinator.

### REVIEWER

17. Print name of Reviewer assigned.
18. Sign and date the review once the review has been completed.

### ORIGINATOR/COMMENT RESPONDER:

19. Sign and date when responses to comments have been completed.

### REVIEWER (if comments are accepted):

20. Record the review draft number (e.g., A, B), of the Concurrence Draft of the Document or Data.
21. Sign and date.

### RESOLVING MANAGER (complete if Reviewer does not concur with a response(s) to a technical comment:

Upon resolution of disputed issue(s):

20. Record the review draft number (e.g., A, B), of the Concurrence Draft of the Document or Data.
21. Mark Reviewer as N/A
22. Print name of Resolving Manager.
23. Sign and date.

**ORIGINATOR/COMMENT RESPONDER:**

22. Sign and date when responses to comments have been completed.

**REVIEWER** (if comments are accepted):

23. Record the review draft number (e.g., 00A, 00B), of the Concurrence Draft of the Document or Data.

24. Sign and date.

**RESOLVING MANAGER** (complete if Reviewer does not concur with a response(s) to a technical comment:

Upon resolution of disputed issue(s):

24. Record the review draft number (e.g., 00A, 00B), of the Concurrence Draft of the Document or Data.

25. Mark Reviewer as N/A

26. Print name of Resolving Manager.

27. Sign and date.



| OSTI-LLNL<br>COMMENT SHEET |                        |                                 |   |                         |
|----------------------------|------------------------|---------------------------------|---|-------------------------|
| 1. Document Title:         |                        |                                 |   | 10. Page _____ of _____ |
| 2. Document No.            | 3. Revision/Mod/Draft: | 4. Date                         | 5. <input type="checkbox"/> QA: QA <input type="checkbox"/> Non QA: N/A |                         |
| 6. Reviewer:               |                        |                                 |   |                         |
| 7. COMMENT NO.             | 8. SEC/PARA /PAGE NO.  | 9. COMMENT/SUGGESTED RESOLUTION | 11. RESPONSE  | 12. ACCEPT <sup>1</sup> |
|                            |                        |                                 |   |                         |

1. Leave blank if Reviewer does not accept the response.

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## INSTRUCTIONS FOR COMPLETING THE COMMENT SHEET

### ORIGINATOR/REVIEW COORDINATOR:

- a. Record the title of Document to be reviewed.
- b. Record the Document Identifier or number of the Document to be reviewed (e.g., OSTI-LLNL-QIP-2.0).
- c. Record the proposed revision/modification/draft number.
- d. Record the date the document was generated.
- e. Identify the Quality Assurance (QA) designator (for reviews of a QA document/data, enter "QA"; for reviews of a non-QA document/data, enter "N/A").
- f. Identify the Reviewer.

### REVIEWER

- g. Identify the number of the comment.
- h. Identify the section/paragraph/page number, as applicable, showing where within the document the comment applies.
- i. Identify the review comment and suggested resolution, if appropriate.
- j. Once completed, identify the page number and total number of pages associated with the completed review.

### ORIGINATOR/COMMENT RESPONDER:

- k. Provide a response to all technical comments.

### REVIEWER

12. Provide initials/date for each accepted response. If the response is unacceptable and an agreement cannot be reached between the Reviewer and the Originator/Comment Responder, elevate the open review item (s) to successively higher levels of management and ultimately to the PM (or designee) for resolution.

**RESOLVING MANAGER** (complete if Reviewer does not concur with a response(s) to a technical comment)

13. Upon discussing the unresolved technical comment(s) with the parties involved, provide resolution of disputed issues(s) and document the resolution on the Comment Sheet, review copy mark-up, or electronically. Indicate the Complete the Concurrence and Dispute Resolution sections on the Review Record per instructions in